

OCT 14 2003

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0623.0730002/LBB/BJD/SJEAPPLICATION NO.  
10/024,597APPLICANT  
Cottingham *et al.*FILING DATE  
December 21, 2001GROUP  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
SDP	AN3	WO 97/07668	March 6, 1997	WIPO	—	—	Yes No
SDP	AO3	WO 97/07669	March 6, 1997	WIPO	—	—	Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

SDP	AR	13	Palmiter, R.D. <i>et al.</i> , "Dramatic growth of mice that develop from eggs microinjected with metallothionein-growth hormone fusion genes," <i>Nature</i> 300:611-615, MacMillan Journals Ltd. (1982).
SDP	AS	13	Maga, E.A. and Murray, J.D., "Mammary Gland Expression of Transgenes and the Potential for Altering the Properties of Milk," <i>Biotechnol.</i> 13:1452-1458, Nature Publishing Company. (December, 1995).
	AT		

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*Scott D. Prich*DATE CONSIDERED  
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
SDP	AA1	5,322,775	06/21/1994	Clark et al.	435	69.1	11/22/1991
	AB1	5,366,894	11/22/1994	Clark et al.	435	320.1	11/22/1991
	AC1	5,476,995	12/19/1995	Clark et al.	800	2	08/18/1992
	AD1	5,610,053	03/11/1997	Chung et al.	435	172.3	07/29/1994
	AE1	5,620,923	04/15/1997	Rechsteiner et al.	435	69.7	04/03/1992
	AF1	5,650,503	07/22/1997	Archibald et al.	536	23.5	12/20/1994
	AG1	5,827,690	10/27/1998	Meade et al.	435	69.6	12/20/1993
	AH1	5,861,299	01/19/1999	Archibald et al.	435	240.2	11/17/1994
	AI1	6,211,427 B1	04/03/2001	Cottingham et al.	800	7	10/08/1996
	AJ						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
SDP	AL1	EP 0 181 634 A2	05/21/1986	Europe	—	—	Yes No
	AM1	WO 88/00239 A1	01/14/1988	WIPO	—	—	Yes No
	AN1	WO 90/05188 A1	05/17/1990	WIPO	—	—	Yes No
	AO1	WO 92/11358 A1	07/09/1992	WIPO	—	—	Yes No
	AP1	WO 92/22644 A1	12/23/1992	WIPO	—	—	Abstract only X Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

SDP.	AR	1	Brignon, G. and Ribadeau-Dumas, B., "A new method for human milk protein separation," <i>Biochimie</i> 64:231-235, Masson (1982).
	AS	1	Clark, A.J., et al., "Rescuing Transgene Expression By Co-Integration," <i>Bio/Technol.</i> 10:1450-1454, Nature Publishing Co. (1992).
	AT	1	Curtis, R.A., et al., "Protein-Protein and Protein-Salt Interactions in Aqueous Protein Solutions Containing Concentrated Electrolytes," <i>Biotechnol. Bioeng.</i> 57:11-21, John Wiley & Sons, Inc. (January 1998).

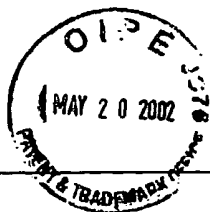
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SDP	✓	AL2 WO 93/25567 A1	12/23/1993	WIPO	✓	—	Yes No
SDP	✓	AM2 WO 94/04672 A1	03/03/1994	WIPO	✓	—	Yes No
	✓	AN2 EP 0 390 330 A2	04/06/1994	Europe	✓	—	Yes No
SDP	✓	AO2 WO 95/27782 A1	10/19/1995	WIPO	✓	—	Yes No
SDP	✓	AP2 EP 0 771 874 A2	05/07/1997	Europe	✓	—	Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

SDP	AR	2	During, K. "A Tightly Regulated System for Overproduction of Bacteriophage T4 Lysozyme in <i>Escherichia coli</i> ," Protein. Expr. Purif. 4:412-416, Academic Press, Inc. (1993).
I	AS	2	Eipper, B.A., et al., "The Biosynthesis of Neuropeptides: Peptide $\alpha$ -Amidation," Annu. Rev. Neurosci. 15:57-85, Annual Reviews Inc. (1992).
V	AT	2	Eipper, B.A., et al., "Peptidylglycine $\alpha$ -amidating monooxygenase: A multifunctional protein with catalytic, processing, and routing domains," Protein Sci. 2:489-497, Cambridge University Press (1993).

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SDP	✓	AL3 WO 97/42835 A1	11/20/1997	WIPO	—	—	Yes No
SDP	✓	AM3 WO 00/29588 A1	05/25/2000	WIPO	—	—	Yes No
		AN					Yes No
		AO					Yes No
		AP					Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

SDP	AR	2	Fischer, B., et al., "Physiological consequence of expression of soluble and active hen egg white lysozyme in <i>Escherichia coli</i> ," <i>Appl. Microbiol. Biotechnol.</i> 39:537-540, Springer-Verlag (1993).
↑	AS	2	Goldman, A.S., et al., "Immunologic factors in human milk during the first year of lactation," <i>J. Pediatr.</i> 100:563-567, C.V. Mosby Co. (1982).
↓	AT	2	Han, K.-K., et al., "Current Developments in Chemical Cleavage of Proteins," <i>Int. J. Biochem.</i> 15:875-884, Pergamon Press Ltd. (1983).

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	AO						Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
SDP	AR	4	Houdebine, L.-M., "Production of pharmaceutical proteins from transgenic animals," J. Biotechnol. 34:269-287, Elsevier Science B.V. (1994).
✓	AS	4	Ibrahimi, I.M., et al., "Determinants for protein translocation across mammalian endoplasmic reticulum. Membrane insertion of truncated and full-length prelysozyme molecules," Eur. J. Biochem. 155:571-576, Springer International (1986).
✓	AT	4	Jacquot, J., et al., "Identification of Different Molecular Forms of Human Airway Lysozyme," Anal. Biochem. 160:227-232, Academic Press, Inc. (1987).

EXAMINER <i>Surt D. Priho</i>	DATE CONSIDERED <i>5/4/04</i>
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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

SDP.	AR	5	Jespers, L., et al., "Overexpression of the phage lambda lysozyme cloned in <i>Escherichia coli</i> : use of a degenerative mixture of synthetic ribosome binding sites and increase of the protein stability in vivo," <i>Protein Eng.</i> 4:485-492, Oxford University Press (1991).
↓	AS	5	Lee, S.H. and de Boer, H.A., "Production of biomedical proteins in the milk of transgenic dairy cows: the state of the art," <i>J. Control. Rel.</i> 29:213-221, Elsevier Science B.V. (1994).
↓	AT	5	Lindahl, L., and Vogel, H.J., "Metal-Ion-Dependent Hydrophobic-Interaction Chromatography of $\alpha$ -Lactalbumins," <i>Anal. Biochem.</i> 140:394-402, Academic Press, Inc. (1984).

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G. D. Prieto

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

SDP ↓	AR	6	Lollike, K., et al., "Purification of Lysozyme from Human Neutrophils, and Development of an ELISA for Quantification in Cells and Plasma," <i>Leukemia</i> 9:206-209, Stockton Press (1995).
	AS	6	Lönnerdal, B., et al., "A longitudinal study of the protein, nitrogen, and lactose contents of human milk from Swedish well-nourished mothers," <i>Am. J. Clin. Nutr.</i> 29:1127-1133, American Society of Clinical Nutrition (1976).
	AT	6	McCreath, G.E., et al., "Preparation and use of ion-exchange chromatographic supports based on perfluoropolymers," <i>J. Chrom. A.</i> 773:73-83, Elsevier Science B.V. (1997).

EXAMINER <i>Shirley D. Smith</i>	DATE CONSIDERED <i>5/4/04</i>
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

SDP.	AR	2	McKee, C., et al., "Production of biologically active salmon calcitonin in the milk of transgenic rabbits," <i>Nature Biotechnol.</i> 16:647-651, Nature Publishing Co. (July 1998).
↓	AS	2	Noppe, W., et al., "Simple two-step procedure for the preparation of highly active pure equine milk lysozyme," <i>J. Chrom. A</i> 719:327-331, Elsevier Science B.V. (1996).
↓	AT	2	Okun, M.M., et al., "Truncations of a Secretory Protein Define Minimum Lengths Required for Binding to Signal Recognition Particle and Translocation across the Endoplasmic Reticulum Membrane," <i>J. Biol. Chem.</i> 265:7478-7484, American Society for Biochemistry and Molecular Biology, Inc. (1990).

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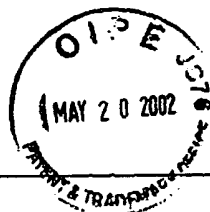
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

SDP	AR	8	Paleyanda, R.K., et al., "Transgenic pigs produce functional human factor VIII in milk," Nature Biotechnol. 15:971-975, Nature Publishing Co. (1997).
-	AS	8	Prasad, R.V., et al., "Amino Acid Sequence of Rat $\alpha$ -Lactalbumin: A Unique $\alpha$ -Lactalbumin," Biochemistry 21:1479-1482, American Chemical Society (1982).
V.	AT	8	Pursel, V.G., et al., "Genetic Engineering of Livestock," Science 244:1281-1288, American Association for the Advancement of Science (1989).

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	AP						Yes No

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SDP	AR	2	Pursel, V.G. and Rexroad, C.E. Jr., "Status of Research with Transgenic Farm Animals," J. Anim. Sci. 71:10-19, American Society of Animal Science (1993).
↓	AS	2	Ray, M.V.L., et al., "Production of Recombinant Salmon Calcitonin by In Vitro Amidation of an Escherichia coli Produced Precursor Peptide," Bio/Technol. 11:64-70, Nature Publishing Co. (1993).
↓	AT	2	Sloane, R.P., et al., "Expression and purification of a recombinant metal-binding T4 lysozyme fusion protein," J. Biotechnol. 49:231-238, Elsevier Science B.V. (1996).

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SDP	AR	10	Vachier, M.C., et al., "Isolation of hen egg white lysozyme, ovotransferrin and ovalbumin, using a quaternary ammonium bound to a highly crosslinked agarose matrix," J. Chrom. B. 664:201-210, Elsevier Science B.V. (1995).
I	AS	10	Van Heeke, G., et al., "Gene Fusions with Human Carbonic Anhydrase II for Efficient Expression and Rapid Single-Step Recovery of Recombinant Proteins: Expression of the <i>Escherichia coli</i> F <sub>1</sub> -ATPase $\epsilon$ Subunit," Prot. Exp. Purif. 4:265-274, Academic Press, Inc. (1993).
V	AT	10	Vasstrand, E.N. and Jensen, H.B., "Affinity chromatography of human saliva lysozyme and effect of pH and ionic strength on lytic activity," Scand. J. Dental Res. 88:219-228, Munksgaard (1980).

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SDP	AR	11	Vilotte, J.-L., et al., "Efficient tissue-specific expression of bovine $\alpha$ -lactalbumin in transgenic mice," <i>Eur. J. Biochem.</i> 186:43-48, Springer International (1989).
1	AS	11	Winters, M.A., et al., "Protein Purification with Vapor-Phase Carbon Dioxide," <i>Biotechnol. Bioeng.</i> 62:247-258, John Wiley & Sons, Inc. (February 1999).
2	AT	11	Wold, F., "In Vivo Chemical Modification of Proteins (Post-Translational Modification)," <i>Ann. Rev. Biochem.</i> 50:783-814, Annual Reviews, Inc. (1981).

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SDP	AR	12	Wright, G., et al., "High Level Expression of Active Human Alpha-1-Antitrypsin in the Milk of Transgenic Sheep," <i>Bio/Technol.</i> 9:830-834, Nature Publishing Co. (1991).
↓	AS	12	NCBI Entrez, Genbank Accession No. X14008, from Sippel, A.E., National Center for Biotechnology Information (1997).
↓	AT	12	Unverified English language abstract of EP 0 590 530 A2 (Document AN2), Derwent World Patent Index (Dialog File 351), Derwent WPI Acc. No. 94-111012/14, Derwent Info Ltd. (1997).

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